

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	CIV. NO.05-73407
	)	
v.	)	HONORABLE DENISE PAGE HOOD
	)	
Various blood glucose test	)	MAGISTRATE JUDGE STEVEN D. PEPE
strips(BGTS), etc.	)	
	)	
	)	
Defendants.	)	

**CONSENT DECREE OF CONDEMNATION**

WHEREAS, on September 2, 2005, the United States of America ("Plaintiff"), by and through its attorney, Stephen J. Murphy, United States Attorney for the Eastern District of Michigan, filed a verified Complaint for Forfeiture ("Complaint") in this Court against the above-captioned articles, which alleges that said articles are adulterated and/or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act ("the Act");

WHEREAS, the United States Marshal for this District seized the above-captioned articles pursuant to a Summons Warrant of Arrest of Property and Notice In Rem issued by this Court;

WHEREAS, on September 30, 2005, H&H Wholesale Services, Inc. and Door to Door Medical Supply, Inc. (collectively, "Claimant") intervened and filed a Claim to all of the seized articles;

WHEREAS, a Consent Decree of Condemnation was previously signed by the parties and entered by this Court with respect to

the three lots of ONETOUCH ULTRA blood glucose test strips that were seized on September 2, 2005 at 333 Park Street, Troy, Michigan;

WHEREAS, this second Consent Decree of Condemnation (hereinafter, "Consent Decree" or "Decree") pertains only to the ONETOUCH ULTRA blood glucose test strips that were seized on September 2, 2005 at 6775 East Ten Mile Road, Centerline, Michigan (hereinafter, "the Articles");

WHEREAS, Claimant affirms that it is the sole owner of the Articles, that no other person has an interest in the Articles, and that it will indemnify and hold Plaintiff harmless should any party or parties hereafter file or seek to file a statement of interest, or to intervene in this action and obtain or defend any part of the Articles subject to this Decree;

WHEREAS, Claimant, without admitting the allegations in the Complaint, now consents to the entry of this Consent Decree of Condemnation without contest and before any testimony has been taken; and

WHEREAS, Plaintiff consents to the entry of this Decree, and the Court being fully advised of the basis thereof, it is now ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 334.

2. The Complaint alleges that the Articles are misbranded within the meaning of 21 U.S.C. § 352(o) and adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B).

3. The Articles are hereby condemned pursuant to 21 U.S.C. § 334, and forfeited to Plaintiff.

4. Pursuant to 21 U.S.C. § 334(e), Claimant shall pay to the United States all court costs and fees, storage, and other proper expenses to date, and such additional expenses as may hereinafter be incurred and taxed.

5. Upon notification from the United States Attorney, the United States Marshal for this District shall release the Articles from his custody to the custody of the Claimant for the sole purpose of bringing the Articles into compliance with the law, if Claimant, within twenty (20) days from the date of this Decree, (a) pays in full the court costs, fees, and storage and other proper expenses of this proceeding to date as described in Paragraph 4 of this Decree; and (b) executes and files with the Clerk of this Court a good and sufficient penal bond in the amount of seventy-five thousand dollars (\$75,000.00). Claimant shall satisfy the requirement of posting a penal bond by depositing seventy-five thousand dollars (\$75,000.00) into the registry of this Court. The funds shall be deposited in accordance with Rule 67 of the Federal Rules of Civil Procedure, and applicable statutes and local rules. The Clerk of Court

shall deposit the funds in an interest bearing account, pursuant to Local Rule 67.1, and shall deduct from the account any fee authorized by the Judicial Conference of the United States. Release of the funds to Claimant shall occur upon Court order following Claimant's abiding by and performing the terms and conditions of this Decree.

6. After depositing the funds into the registry of this Court as specified in Paragraph 5, Claimant shall give written notice to FDA at the Detroit District Office, U.S. Food and Drug Administration, 300 River Place, Suite 5900, Detroit, Michigan 48207, that Claimant, at its own expense, is prepared to attempt to bring the Articles into compliance with the law under the supervision of a duly authorized representative(s) of the United States Department of Health and Human Services ("FDA representative").

7. Claimant shall not commence, permit any other person to commence, or cause any other person to commence attempting to bring any of the Articles into compliance with the law unless and until Claimant submits a written statement to FDA detailing the proposed plan to bring the Articles into compliance and receives written authorization from FDA to commence attempting to bring the Articles into compliance with the law.

8. Claimant shall at all times, until the Articles have been released by an FDA representative, retain the Articles

intact for examination or inspection by the FDA representative, and shall maintain the records or other proof necessary to establish the identity of the Articles to the satisfaction of the FDA representative.

9. Claimant shall at no time, and under no circumstances whatsoever directly or indirectly, cause or permit the shipment, sale, offer for sale, or other disposal of any part of the Articles unless and until an FDA representative has had free access to the Articles to take any samples or make any examinations that are deemed necessary, and the FDA representative has released, in writing, such articles for shipment, sale, or other disposition.

10. If requested by an FDA representative, Claimant shall furnish duplicate copies of invoices of sale of the released Articles, or such other evidence of disposition as an FDA representative requests.

11. Within ninety (90) days after receiving initial authorization pursuant to Paragraph 7, Claimant shall complete its attempt to bring the Articles into compliance with the law under the supervision of the FDA representative, and in a manner acceptable to FDA. Claimant shall destroy, at Claimant's sole expense and under the supervision of the FDA representative, any Article that has not been brought into compliance within the

ninety (90) day period specified in this Paragraph within ten (10) days thereafter, and shall make due return to this Court.

12. Claimant shall not destroy or dispose of, permit another person to destroy or dispose of, or cause another person to destroy or dispose of the Articles or any part of the Articles in a manner contrary to the provisions of the Act, or other laws of the United States, or of any State or Territory (as defined in the Act), in which they are disposed of.

13. The United States Attorney for this District, upon being advised by an FDA representative that the Articles have been brought into compliance with the law and the requirements of this Decree or destroyed in compliance with this Decree and the law, and that Claimant has paid all costs as of that date, will transmit such information to the Clerk of this Court, whereupon the funds deposited in the registry of this Court shall be returned upon Court order.

14. If within thirty (30) days of the entry of this Decree, Claimant does not avail itself of the opportunity to repossess the Articles as set forth in Paragraph 5 above, the United States Marshal for this District shall destroy the Articles and make due return to this Court regarding their disposition. Claimant shall bear the costs of destruction.

15. Claimant shall reimburse the United States for the costs of supervising Claimant's compliance with the terms of this

Decree, including all inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Decree, at the standard rates prevailing at the time the activities are accomplished. As of the date this Decree is signed by the parties, these rates are: \$76.10 per hour and fraction thereof per representative for inspection work; \$91.18 per hour and fraction thereof per representative for analytical work; \$0.445 per mile for travel expenses; the government rate or equivalent for travel by air; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, per representative, for subsistence expenses where necessary. In the event that the standard rates generally applicable to FDA supervision, inspection, review, examination, or analysis are modified, these rates shall be increased or decreased without further order of the Court.

16. If Claimant fails to abide by and perform all of the terms and conditions of this Decree, then the funds deposited as provided in Paragraph 5 of this Decree shall, on motion of Plaintiff in this proceeding and order of the Court, be forfeited in their entirety and judgment entered in favor of Plaintiff. If Claimant breaches any term or condition of this Decree, then Claimant at its own expense, shall immediately return the Articles to the United States Marshal for this District or otherwise dispose of them pursuant to an order of this Court. In

the event that return of the articles becomes necessary pursuant to this paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by Plaintiff.

17. Claimant shall abide by the decisions of FDA, which shall be final. All decisions specified in this Decree shall be vested in the discretion of FDA. When contested by Defendants, FDA decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard, 5 U.S.C.

§ 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

18. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to the proper disposition of this proceeding.

SO ORDERED:

Dated this 3<sup>rd</sup> day of February, 2006.

s/ DENISE PAGE HOOD  
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree.

STEPHEN J. MURPHY  
United States Attorney

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s/Howard B. Goldman (w/consent)  
Howard B. Goldman  
on behalf of Claimants  
H&H Wholesale Services, Inc.  
and Door to Door Medical  
Supply, Inc.

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